CLINICAL RESEARCH STUDIES

Prosthetic above-knee femoropopliteal bypass grafting: Five-year results of a randomized trial

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Purpose: This trial was designed to identify factors affecting patency rates of primary prosthetic above-knee femoropopliteal bypass grafts at 5 years.

Methods: A multi-institutional, prospective trial randomized 240 patients to compare patency rates of Gore-tex and Hemashield above-knee femoropopliteal bypass grafts at 5 years. Univariate comparisons of patency between levels of each prognostic variable were made with the Kaplan-Meier method. Variables that had a univariate *P* value less than .25 or those known to be important were submitted to a Cox regression analysis.

Results: The patient survival rate at 5 years was 59.4%. There were no differences in primary or secondary patency rates at 5 years between the two graft materials (primary, 45% vs 43% and secondary, 68% vs 68%). The risk for graft occlusion was significantly increased for patients younger than 65 years (2.1; $P = .001$) and for grafts with a diameter less than 7 mm (1.65; $P = .0219$). Variables with no apparent independent effect on patency rates were smoking status, runoff, diabetes mellitus, sex, presenting symptoms, and postoperative treatment with aspirin or Coumadin. Noninvasive test results were not predictive of subsequent graft function.

Conclusion: Although the type of prosthetic used for above-knee femoropopliteal bypass grafts does not affect 5-year patency rates, age and graft size do influence results. These factors should be considered before a prosthetic bypass grafting procedure. Furthermore, these data should serve as a contemporary standard, with which evolving and conventional procedures can be compared. (J Vasc Surg 2000;31:417-25.)

Three-year results of a multicenter randomized prospective clinical trial determined that collagen-impregnated knitted polyester velour (HMDV; Hemashield Microvel Double Velour, Meadox Medicals, Oakland, NJ) and thin-walled expanded polytetrafluoroethylene (Gore-tex; W.L. Gore, Flagstaff, Ariz) performed equally well as a conduit from the common femoral artery to the above-knee popliteal artery.[1] This interim report identified patient age, tobacco use, and graft diameter as variables that affected graft survival.

Patency survival and the variables affecting patency of above-knee femoropopliteal prosthetic bypass grafts at 5 years are examined in this final report. This randomized prospective trial provides information that, if heeded, should improve selection and operative results in the broad category of patients eligible for this procedure. In addition, this prospective series provides a current standard with which newer, less invasive procedures and conventional autologous venous bypass grafts can be compared.

MATERIALS AND METHODS

Patients. The institutional review boards of each of the eight participating institutions approved the experimental protocol. The first

Competition of interest: nil.

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Table I. Patient survival

Interval (mo)	No. alive at beginning of interval	No. of deaths during interval	Withdrawn during interval: Time	Withdrawn during interval: LTF	Total withdrawn during interval	Interval survival rate	Cumulative survival rate (%)	SE (%)
0 to 1	240	4	3	4	7	0.983	98.31	0.83
1 to 3	229	2	5	5	10	0.991	97.43	1.03
3 to 6	217	8	15	10	25	0.961	93.62	1.61
6 to 12	184	4	21	18	39	0.976	91.34	1.98
12 to 18	141	9	15	5	20	0.931	85.07	2.77
18 to 24	112	1	21	3	24	0.990	84.22	3.16
24 to 36	87	9	24	3	27	0.878	73.90	4.05
36 to 48	51	5	16	0	16	0.884	65.31	5.39
48 to 60	30	2	16	0	16	0.909	59.37	6.91

LTF, Lost to follow-up.

patient was enrolled on Nov 12, 1991, and the last patient was enrolled on Jan 31, 1996. Patients were eligible for this trial when they had: (1) an angiographically demonstrated superficial femoral artery occlusion with reconstitution of a popliteal segment above the knee, and (2) not undergone any earlier infrainguinal vascular procedures. Patients who had undergone earlier aortofemoral, iliofemoral, and femorofemoral bypass grafting procedures were eligible. Adjunctive inflow procedures were not allowed at the time of the femoropopliteal bypass grafting procedure. Two hundred forty patients undergoing primary above-knee femoropopliteal bypass grafting procedures at eight institutions (Hahnemannn University Hospital [66], University of Rochester [58], Norfolk General Hospital [37], Jewish General Hospital and Royal Victoria Hospitals in Montreal, Quebec [28], Montefiore Medical Center [16], Massachusetts General Hospital [16], Ocshner Clinic [7], and Baptist Memorial Hospital in Memphis [2]) were centrally randomized to receive either Gore-tex or HMDV grafts by the operating surgeon, after informed consent was obtained. Men comprised 60.2% of the HMDV and 60.7% of the Gore-tex groups. The women were older than the men, 69.3 versus 65.7 years (SE, 0.3; $P = .002$). Graft diameter and the type of postoperative anticoagulation, if any, was determined by the operating surgeon. No attempt was made to monitor patient compliance with any anticoagulation regimen. Data pertaining to patient risk factors (diabetes mellitus, smoking, hypertension, and hyperlipidemia) and vascular risk factors (level of ischemia, runoff status, preoperative ankle-brachial index) were prospectively collected by study coordinators and centrally entered into a database designed and managed by Boston Scientific Vascular for this study.

Patients were observed at 1, 3, 6, 12, 18, and 24 months after operation and then at yearly intervals with clinical examination and ankle-brachial pressure ratios. The original protocol allowed for additional noninvasive investigations at the discretion of the surgeon, but the protocol was amended in 1994 to require both ankle-brachial pressure measurements and duplex scans of the grafts at each follow-up visit. This change was based on preliminary data that suggested a predictive value for the duplex scan before patency failure. The management of graft occlusion was left to the discretion of each investigator.

Local study coordinators forwarded reports to Boston Scientific Vascular, and site visits were made regularly to monitor compliance. The database was reconfigured post hoc to conform to the revised recommended standards for reports dealing with lower-extremity ischemia.[2]

Statistical analysis. Calculations were done during the study design period to provide for sufficient numbers of patients to detect a difference in the two graft materials, with a power of at least 0.80 and an alpha of 0.05. The group comparison is the strongest inference, because this is determined prospectively by the study protocol. All other analyses are post hoc, for the purpose of investigating factors possibly influencing patency survival.

Univariate comparisons of patency between levels of each prognostic variable were made with the Kaplan-Meier estimate.[3] Variables that had a univariate P value less than .25 or those known to be important but failing to meet the critical alpha level were submitted to a Cox regression analysis to determine the independent, multivariable predictors of patency. All first order interactions were tested in this model.

Table II. Primary patency data, entire series

Interval (mo)	No. at risk at start of interval	No. failed during interval	Withdrawn during interval			Total withdrawn	Interval patency rate	Cumulative patency rate (%)	SE (%)
			Time	LTF	Death				
0 to 1	240	4	3	4	4	11	0.983	98.29	0.83
1 to 3	225	5	4	4	2	10	0.977	96.06	1.27
3 to 6	210	14	6	9	8	23	0.929	89.29	2.02
6 to 12	173	19	9	11	3	23	0.882	78.78	2.76
12 to 18	131	9	10	4	8	22	0.925	72.87	3.32
18 to 24	100	8	15	2	0	17	0.913	66.50	3.85
24 to 36	75	2	18	1	8	27	0.967	64.34	4.44
36 to 48	46	5	12	0	5	17	0.867	55.76	5.47
48 to 60	24	4	8	0	2	10	0.789	44.02	6.72
Totals		70	85	35	40	160			

LTF, Lost to follow=up.

RESULTS

Patient and graft survival

Forty-four patients died during the study period. The 5-year patient survival rate in this series was 59.4% (Table I). Associated cardiovascular disease was responsible for 26 deaths, six patients died of cancer, four patients died of miscellaneous causes, and eight patients died of undetermined causes. There were four deaths within 30 days of operation. Two patients died of cardiac arrest (days 7 and 16), another patient died of a pulmonary embolus (day 9), and one patient died after a stroke (day 13).

The mean follow-up period was 638 days ± 24.24 SE. The 5-year cumulative primary patency rate was 44% (Table II). The secondary patency rate at this same interval was significantly higher, 67.3% (P = .5). Seventy patients had at least one graft occlusion. The occlusion was treated immediately in 29 patients by means of either thrombolysis (22) or thrombectomy (7) when urgent revascularization was required. The degree of ischemia at the time of graft occlusion did not correlate with the original indication for operation. Some patients originally undergoing surgery for claudication had rest pain when their grafts occluded. Thrombolysis alone was successful in 10 patients, whose grafts remained patent for the remainder of the study. Thrombolysis was unsuccessful or lesions were identified that required placement of a new bypass graft in 11 patients. One patient required a below-the-knee amputation after unsuccessful thrombolysis. Of the seven patients who underwent immediate thrombectomy, the grafts remained patent in four patients, one patient required a new bypass graft, and two patients were left untreated after rethrombosis occurred. Data were available in 26 patients after either successful thrombolysis or operative revision, leaving us unable to comment on the cause of failure (Table III). Popliteal artery lesions, either representing anastomotic stenoses or progression of occlusive disease, were thought to be the cause of failure in 13 of the 26 patients. No anatomic cause was identified in 12 of the 26 grafts successfully treated.

Table III. Documented causes of graft failure

Cause of failure	Thrombolysis group (N = 19)	Operative group (N =7)
Anastomotic stenosis		
Proximal	0	0
Distal	6	2
Progression disease		
Iliac artery stenosis	1	0
Popliteal artery stenosis	4	1
None identified	8	4

Forty-one other patients had initial graft occlusion that was not associated with limb-threatening ischemia, and treatment was deferred. New bypass grafts were subsequently required in 20 of these patients for disabling claudication or rest pain. The remaining 21 patients chose to live with their symptoms rather than undergo another procedure.

There were 10 amputations (4%) in this series, five in each graft grouping. Six of the 10 amputations occurred within the first month, and all amputations occurred within the first year. In eight of the 10 patients, threatened tissue loss was the indication for surgery. One patient requiring an amputation entered the trial as a claudicator. In this patient, randomized to HMDV, a hypercoagulable state developed because of advanced cancer. One other patient entered the study with ischemic rest pain.

Table IV. Patient risk factors

	HMDV		*Gore-tex*		*Total*	
	N	*%*	*N*	*%*	*N*	*%*
Diabetes mellitus						
None	69	59.0	53	43.4	122	51.0
Adult, diet	19	16.2	30	24.6	49	20.5
Adult, insulin	27	23.1	33	27.0	60	25.1
Juvenile	2	1.7	6	4.9	8	3.3
Tobacco use						
None	48	41.0	45	36.9	93	38.9
None, but smoked in the past 10 years	33	28.2	33	27.0	66	27.6
Current, < 1 pack per day	22	18.8	30	24.6	52	21.8
Current, > 1 pack per day	14	12.0	14	11.5	28	11.7
Hypertension						
None	31	26.5	48	39.3	79	33.1
Easily controlled with single drug	41	35.0	40	32.8	81	33.9
Controlled with 2 drugs	30	25.6	25	20.5	55	23
Requires > 2 drugs	15	12.8	9	7.4	24	10.0
Lipid level						
Normal	74	63.2	69	56.6	143	59.8
Mild, diet controlled	28	23.9	41	33.6	69	28.9
Type II, III, or IV, strict diet	5	4.3	3	2.5	8	3.3
Requires diet and drugs	10	8.5	9	7.4	19	7.9

HMDV, Collagen-impregnated knitted polyester velour grafts; *Gore-tex,* thin-walled expanded polytetrafluoroethylene grafts.

Table V. Level of ischemia and angiographic status

	HMDV		*Gore-tex*		*Total*	
	N	*%*	*N*	*%*	*N*	*%*
Level of ischemia*						
Acute, viable	3	4.2	1	0.8	4	1.7
Acute, threatened	2	1.7	2	1.6	4	1.7
Reversible	0	0.0	0	0.0	0	0.0
Chronic, mild claudication	2	1.7	1	0.8	3	1.3
Chronic, moderate claudication	26	22.0	38	31.1	64	26.7
Chronic, severe claudication	40	33.9	35	28.7	75	31.1
Chronic, ischemic rest pain	17	14.4	9	7.4	26	10.8
Chronic, minor tissue loss	28	23.7	32	26.2	60	25.0
Chronic, major tissue loss	0	0.0	4	3.3	4	1.7
Outflow status*						
3 vessels	29	25.0	33	27.3	62	26.2
2 vessels	45	38.8	47	38.8	92	38.8
1 vessel	31	26.7	36	29.8	67	28.3
Blind popliteal	11	9.5	5	4.1	16	6.8
Preoperative ankle-brachial index*	0.5		0.52		0.51	

**P* values not significant between Gore-tex and HMDV groups.
HMDV, Collagen-impregnated knitted polyester velour grafts; *LTF,* lost to follow-up.

Hemashield Microvel Double Velour Versus Gore-tex

The patient and vascular risk factors are evenly distributed between the two graft populations, with the exception of diabetes mellitus, which was more common in the Gore-tex group (P = .04), and hypertension, which was more common in the HMDV group (P = .0195; Tables IV and V). The 5-year cumulative patency rates (Tables VI and VII) were 45.3% for HMDV and 42.6% for Gore-tex (P = NS). Similarly, no difference was noted in secondary patency rates at 5 years (68.4% vs 67.6%). The incidences of wound complications (ie, graft infection [2.7% vs 1.7%], wound infection [6.3% vs 10.1%], and seromas [4.5% vs 2.5%]) were similar for HMDV and Gore-tex. Also, the incidences of

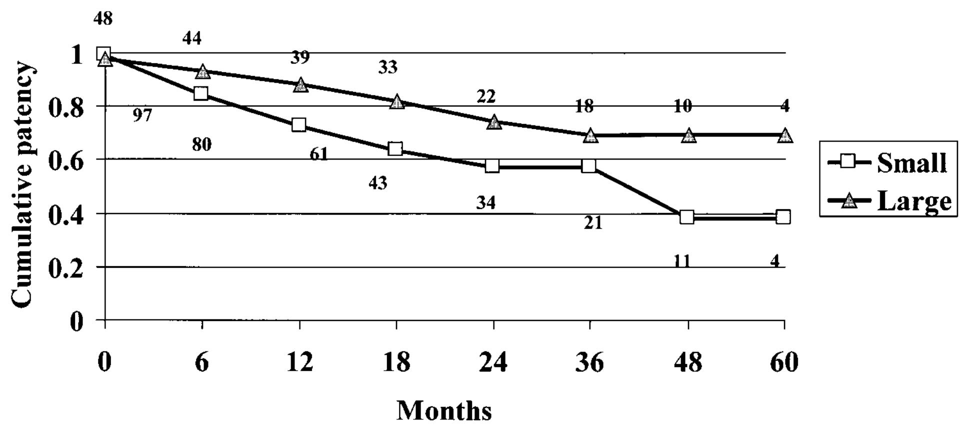

Fig 1. The Kaplan-Meier data for cumulative graft patency for large and small diameter grafts.

myocardial infarction and/or congestive heart failure (8.1% vs 7.5%), stroke (3.6% vs 0.8%), and deep venous thrombosis (3.6% vs 1.7%) were similar.

Risk factors for patency failure

Variables that did not affect patency survival were smoking, hyperlipidemia, runoff, diabetes mellitus, hypertension, level of limb ischemia, and the type of graft implanted.

Age

Patients were arbitrarily divided into a young group, the members of which were younger than 65 years (N = 139), and an old group, the members of which were 65 years or older (N = 101). The 5-year patency rate of the old group exceeded that of the young group, 55.2% versus 36.2% (P = .0491). The 5-year patency rate of grafts in young men was significantly less than the rate in old men, 42.2% vs 70.2%, whereas no difference in patency was detected in the female population stratified by age, 26.7% versus 26.7%. Age was a significant variable, whether used as a categorical (younger than 65 years, P = .0010) or a continuous (years, P = .0128) value.

Graft diameter. Graft diameters were classified as small (5 or 6 mm) or large (7 or 8 mm). Either 5- or 6-mm grafts were used in 71.6% of the series. Although there was a tendency to use small grafts more often in female patients, this was not a statistically significant finding. Small graft size was an important variable affecting patency (P = .0143), but its effect was sex dependent. The 5-year cumulative patency rates for men with small and large grafts were 37.9% and 69.1%, respectively (P = .031). Similar comparisons in women show that the 5-year cumulative patency rates were 45% for both large and small grafts. The Kaplan-Meier data for cumulative graft patency for large and small diameter grafts are shown in Fig 1.

Runoff. “Good” run-off was defined as having the popliteal artery and two or three tibial vessels patent to the foot. “Poor” runoff existed when either one tibial vessel was patent to the foot or the popliteal artery ended blindly. The 5-year cumulative patency rate for grafts with good runoff was 34.9% and was lower than the cumulative patency rate of 65.8% for grafts with poor runoff, but this difference did not reach statistical significance.

Smoking. Smoking was not a univariate predictor of graft patency (P = .26). Any apparent effect is a reflection of the higher incidence of smoking in the population younger than 65 years. Patency at 1200 days for cohorts was the following (predicted probability ± SE): Age younger than 65 years, non-smoker, 51% ± 12%; Age older than 65 years, non-smoker, 68% ± 6%; Age younger than 65 years, smoker, 44% ± 10%; Age older than 65 years, smoker 68% ± 10%; P = .013. Smoking, by itself, without any other variable, did not remain significant in a Cox model of patency.

Noninvasive laboratory testing. Ankle-brachial indices and velocity data from duplex scans were analyzed to identify abnormalities that might predict graft thrombosis. These data were compared with velocities associated with failing autogenous venous bypass grafts. Peak systolic velocity, either as a maximum or minimum number or a ratio between the two, or decreases in the ankle-to-brachial pressure index had no correlation with subsequent graft thrombosis. Because the duplex scans were an addendum to the protocol, sufficient data were not available to make any statistical conclusions, because most graft thromboses occurred before the protocol change.

Table VI. Primary patency data, HMDV

Interval (mo)	*No. at risk at start of interval*	*No. failed during interval*	*Withdrawn during interval*			*Total withdrawn*	*Interval patency rate*	*Cumulative patency rate (%)*	*SE (%)*
			Time	*LTF*	*Death*				
0 to 1	118	0	2	1	3	6	1.000	100.00	0.00
1 to 3	112	2	2	2	2	6	0.982	98.17	1.26
3 to 6	104	7	4	5	2	11	0.929	91.19	2.65
6 to 12	86	12	5	3	1	9	0.853	77.76	3.95
12 to 18	65	6	5	1	4	10	0.900	69.99	4.76
18 to 24	49	3	9	1	0	10	0.932	65.21	5.49
24 to 36	36	0	7	0	4	11	1.00	65.21	6.41
36 to 48	25	3	5	0	3	8	0.857	55.90	7.42
48 to 60	14	2	5	0	2	7	0.810	45.25	8.9
Totals		35	49	13	21	83			

HMDV, Collagen-impregnated knitted polyester velour grafts; *LTF,* lost to follow-up

Table VII. Primary patency, Gore-tex data

Interval (mo)	*No. at risk at start of interval*	*No. failed during interval*	*Withdrawn during interval*			*Total withdrawn*	*Interval patency rate*	*Cumulative patency rate (%)*	*SE (%)*
			Time	*LTF*	*Death*				
0 to 1	122	4	1	3	1	5	0.967	96.65	1.60
1 to 3	113	3	2	2	0	4	0.973	94.04	2.16
3 to 6	106	7	2	4	6	12	0.930	87.46	3.01
6 to 12	87	7	4	8	2	14	0.913	79.81	3.84
12 to 18	66	3	5	3	4	12	0.950	75.81	4.59
18 to 24	51	5	6	1	0	7	0.895	67.83	5.39
24 to 36	39	2	11	1	4	16	0.935	63.46	6.14
36 to 48	21	2	7	0	2	9	0.879	55.77	8.09
48 to 60	10	2	3	0	0	3	0.765	42.64	10.21
Totals		35	41	22	19	82			

Gore-tex, Thin-walled expanded polytetrafluoroethylene grafts; *LTF,* lost to follow-up.

Cox proportional hazards model

The Cox model analysis is a method that provides likely hypotheses that must be confirmed by means of a study prospectively designed to address these issues. Two hundred thirty-six patients who had all covariates were analyzed after stratification by age as both a categorical (younger than 65 years, older than 65 years) and continuous variable. The hazard ratios are listed in Table VIII. The negative effect of an age younger than 65 years and graft diameter smaller than 7 mm reached statistical significance ($P < .05$); adverse trends were noted in patients with normal blood lipid levels ($P = .07$) and two or three vessels with runoff ($P = .08$).

DISCUSSION

The original intent of this trial was to randomize the two different graft materials. These 5-year results prove that HMDV and Gore-tex grafts do not have different patency rates or, at least, that there is no visible difference above the error of the study. The patency rate of 44% after 5 years is at the lower end of the range reported by other authors for prosthetic grafts to the above-knee popliteal artery[4-6] and considerably lower than the series reported by El-Massry et al.[7] It is hard to compare these series with the current series, because the other series were retrospective analyses of data, and results are often expressed on the basis of operative indication. Our results suggest that if followed for even longer periods, prosthetic bypass grafts would continue to occlude at a rate exceeding that of autogenous venous bypass grafts, which have 5- and 10-year cumulative patency rates of 77%[8] and 50%,[9] respectively. Although this study was not designed to compare prosthetic bypass grafts with autogenous venous bypass grafts or evaluate the concept of preferential use of a prosthetic to save the vein, one cannot escape the disappointing 5-

year results with prosthetic materials. Wilson et al make an effective argument against preferential use of prosthetic grafts.[10] They examined their series of 112 above-knee femoropopliteal bypass grafts and concluded that the 3-year results were superior for autogenous vein, that the amputation rate after graft failure was significantly higher when Gore-tex was used, and that the secondary vein was only rarely needed after Gore-tex failure.

The strong evidence that small-diameter grafts have a greater risk of occlusion is counterintuitive. One would expect that smaller-diameter grafts would have higher flow velocities and fewer failures. Our data do not support this hypothesis. First, there are no data that demonstrate increased flow velocities in 5- and 6-mm grafts, as compared with 7- and 8-mm grafts. Second, our data do not support the hypothesis that graft patency is in any way related to the flow velocities found in these prosthetic grafts. Most of our failures that had objective data regarding the cause of failure were caused by a distal anastomotic problem. The improved patency survival rate for larger diameter grafts is most likely a result of the larger anastomosis lessening the significance of neointimal fibrous hyperplasia. These data strongly support the use of a graft with a diameter of larger than 7 mm whenever possible.

An apparent adverse sex influence on patency survival in women was probably related to the use of smaller grafts. Other studies have also shown that the results of infrainguinal reconstruction in women were comparable with those in men. Harris et al found in a series of 823 infrainguinal arterial reconstructions that mortality, patency, and salvage rates were not statistically different between men and women.[11] Magnant et al found that results were superior in women.

The improved graft patency rates in our patients with poor runoff lends further support to the concept that prosthetic bypass graft patency is not dependent on flow velocities. Contradictory evidence exists about the role of runoff on graft patency. Kram et al evaluated 217 bypass grafts to isolated popliteal segments.[12] They found that the patency rates at 5 years were 59% for saphenous vein and 74% for Gore-tex ($P < .05$). In contrast, El-Massry et al found that the single variable with a significant adverse impact on patency rates of Dacron grafts was poor outflow. No explanation for the variable effect of poor runoff is forthcoming. Nonetheless, this study does demonstrate that a prosthetic above-knee femoropopliteal graft to an isolated popliteal segment is durable.

Table VIII. Cox proportion hazards model constructed by using age as both a categorical and continuous variable

Entering age as a categorical value:

	Risk ratio	*95% CI*	*P value*
Age < 65 years	2.103	1.30, 3.39	.0010
Graft diameter < 7 mm	1.635	0.91, 2.92	.0219
Hyperlipidemia	0.626	0.38, 1.04	.0694
Runoff (2 or 3 vessels)	1.603	1.0, 2.58	.0702

Entering age as a continuous variable:

	Risk ratio	*95% CI*	*P value*
Age (years)	0.974	0.95, 0.99	.0128
Graft diameter < 7 mm	1.753	0.99, 3.11	.0131
Hyperlipidemia	0.63	0.38, 1.05	.0727
Runoff (2 or 3 vessels)	1.561	0.97, 2.50	.0858

The original publication from this group found that smoking had a significant negative impact on graft patency.[1] However, the smoking factor was acknowledged to be confounded with the age factor, because a higher proportion of smokers came from the group of patients younger than 65 years; 85% of the patients younger than 65 years indicated a smoking history, compared with only 47% of the patients older than 65 years. The association of smoking with an increased tendency toward graft occlusion is most likely an adverse effect of a young age on patency. Prendiville et al also noted a decrease in Gore-tex graft patency in patients who continue to smoke after surgery.[13] Cheshire et al measured plasma fibrinogen, lipoprotein (a), and serotonin in patients with infrainguinal bypass grafts[14] and found that patients who smoked had a 61% incidence of graft stenosis, compared with an incidence of only 21% in those patients who did not smoke. Patients in whom a stenosis developed had higher circulating levels of fibrinogen, lipoprotein (a), and 5-hydroxytryptamine. These data make a strong argument for keeping these patients away from tobacco, but a study directed at this issue will be required before a definitive statement can be made.

These 5-year data can be used as a contemporary standard to evaluate newer endovascular procedures designed to treat superficial femoral artery occlusions. Although none has produced results in any way comparable with this series,[15] newer covered stents are at various stages of development and structurally are not very different than a conventional above-knee femoropopliteal prosthetic graft.

Failing prosthetic grafts were only identified in a few instances, despite the frequency of graft surveillance. No statistical conclusions could be reached because of an inadequate sample size, however. Although other authors have reported success with prosthetic graft surveillance,[16,17] these studies really demonstrate that inflow and outflow disease progression that may threaten graft survival can be identified in some patients. Because graft lesions themselves are uncommon in patients with prosthetic bypass grafts, graft surveillance programs akin to those recommended for autogenous grafts are of limited benefit.[18]

Finally, mention must be made of the 5-year patient survival rate of only 59.4%. Our mortality data are no different than those published in 1971 by DeWeese and Rob, who looked at the 5-year results of autogenous venous bypass grafting procedures,[19] and Allen, Barker, and Hines, who examined patients 5 years after their initial visit to the Mayo Clinic for lower-extremity occlusive disease in 1955.[20] Deaths in each of these series, spanning four decades, were mostly caused by cardiac or cerebrovascular illnesses. Perhaps the use of more aggressive screening for and treatment of ischemic heart disease and stroke has not significantly affected the malignant nature of the generalized atherosclerotic process.

CONCLUSION

This series provides a unique data set from contemporary randomized and prospectively placed prosthetic infrainguinal bypass grafts. It validates the original hypothesis that the two graft materials, Gore-tex and HMDV, behave in a similar fashion in a reasonable follow-up period. Perhaps more important, it reveals the adverse relationship between age younger than 65 years and graft thrombosis and the importance of selecting a large-diameter graft, however counterintuitive that choice may seem. Young patients should not have prosthetic bypass grafting for ischemia that does not cause rest pain or threaten tissue loss when the saphenous vein is unavailable, unless the 5-year patency survival rate for prosthetic materials of less than 50% is acceptable.

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